

IN THE UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF DELAWARE

NIPPON SHINYAKU CO., LTD.,

Plaintiff,

v.

SAREPTA THERAPEUTICS, INC.,

Defendant.

SAREPTA THERAPEUTICS, INC. and THE  
UNIVERSITY OF WESTERN AUSTRALIA,

Defendant/Counter-Plaintiffs,

v.

NIPPON SHINYAKU CO., LTD.  
and NS PHARMA, INC.

Plaintiff/Counter-Defendants.

C.A. No. 21-1015 (JLH)

**PUBLIC VERSION**

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**SAREPTA THERAPEUTICS, INC. AND THE UNIVERSITY OF WESTERN  
AUSTRALIA'S RESPONSE TO NS'S CONCISE STATEMENT OF FACTS**



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<b>Abbreviation</b>	<b>Description</b>
'851 Patent	U.S. Patent No. 9,994,851
'590 Patent	U.S. Patent No. 10,227,590
'827 Patent	U.S. Patent No. 10,266,827
'092 Patent	U.S. Patent No. 10,385,092
'461 Patent	U.S. Patent No. 10,407,461
'106 Patent	U.S. Patent No. 10,487,106
'741 Patent	U.S. Patent No. 10,647,741
'217 Patent	U.S. Patent No. 10,662,217
'322 Patent	U.S. Patent No. 10,683,322
ASO	Antisense oligonucleotide
<b><i>Bold and Italic</i></b>	Emphasis added unless indicated otherwise
Ex. ____	Exhibit ____ <sup>1</sup>
NS	Plaintiff/Counter-Defendants Nippon Shinyaku Co., Ltd. and NS Pharma, Inc.
NS Japan	Plaintiff/Counter-Defendant Nippon Shinyaku Co., Ltd.
NS Pharma	Counter-Defendant NS Pharma, Inc.
NS Patents	U.S. Patent Nos. 10,385,092; 10,407,461; 10,487,106; 10,647,741; 10,662,217; 10,683,322
PTO	United States Patent and Trademark Office
Sarepta	Defendant/Counter-Plaintiff Sarepta Therapeutics, Inc.
UWA	Counter-Plaintiff The University of Western Australia
Wilton Patents	U.S. Patent Nos. 9,994,851; 10,227,590; and 10,266,827
Wilton Product Patents	U.S. Patent Nos. 9,994,851; 10,227,590

<sup>1</sup> Refers to Exhibits to the accompanying Declaration of Megan E. Dellinger in Support of Sarepta Therapeutics, Inc. and The University of Western Australia's Replies to Their Motions for Summary Judgment and Motions to Exclude Certain Opinions and Testimony of Plaintiff/Counter-Defendants' Experts.

[REDACTED]

In Support of Its Motion for Summary Judgment Nos. 1-3, Defendant Sarepta Therapeutics, Inc. (“Sarepta”) respectfully submits the following response to Plaintiff’s Counterstatement of Facts. Sarepta disputes any alleged fact unless it is specifically undisputed below.

**I. REPLY IN SUPPORT OF MOTION #1: SUMMARY JUDGMENT OF INFRINGEMENT OF U.S. PATENT NOS. 9,994,851 AND 10,227,590**

- 1. Undisputed.**
- 2. Undisputed.**
- 3. Undisputed.**

II. **REPLY IN SUPPORT OF MOTION #2: SUMMARY JUDGMENT OF NO LOST PROFITS**

1. **Undisputed** for the purposes of this summary judgment motion only.

2. **Undisputed.**

3. **Undisputed.**

4. **Disputed.** Sarepta does not dispute [REDACTED]

[REDACTED] D.I. 426-1 (Ex. 53), NS00036897.

Sarepta does not dispute that an internal [REDACTED]

[REDACTED] D.I. 426-1 (Ex. 52),

NS00036827. Sarepta disputes that [REDACTED]

”

5. **Undisputed.**

6. **Disputed.** NS Pharma does not “ [REDACTED]

because [REDACTED] Ex. 4, 88:25-89:24. [REDACTED]

[REDACTED] D.I. 427-10, ¶114. That said, Sarepta’s motion does not require resolution of this dispute.

7. **Disputed.** NS Japan and NS Pharma have not produced copies [REDACTED]

[REDACTED], and relies solely on the uncorroborated testimony of Mr. Gendron for this assertion. That said, Sarepta’s motion does not require resolution of this dispute.

8. **Disputed.** NS Japan and NS Pharma have not produced copies of [REDACTED]

[REDACTED]

[REDACTED] have actually been submitted. Instead, it relies solely on [REDACTED]

[REDACTED] D.I. 463, ¶8 (citing D.I. 426-1 (Ex. 53), NS00036899 ([REDACTED])).

That said, Sarepta's motion does not require resolution of this dispute.

**9. Undisputed.**

**10. Disputed.** Sarepta disputes that NS Japan [REDACTED]

[REDACTED] As NS Japan admitted, the [REDACTED]

[REDACTED] D.I. 466, ¶2.15 (admitting D.I. 411, ¶2.15). NS Japan also admitted that, while [REDACTED]

[REDACTED] D.I. 463, ¶21. Thus, there is nothing certain about the [REDACTED]

[REDACTED] Sarepta also disputes the characterization of the [REDACTED]

[REDACTED] The [REDACTED]

[REDACTED] D.I. 426-1 (Ex. 53), NS00036897 ([REDACTED]);

*see also* D.I. 411 ¶2.8; D.I. 466 ¶2.8 (admitting "[REDACTED]").

**11. Disputed.** [REDACTED]

[REDACTED] *Compare* Ex. 4, 84:6-10 ([REDACTED])

[REDACTED]), 35:2-10, *with*

Ex. 7, 137:12-138:1 ([REDACTED]), 16:22-17:8.

That said, Sarepta's motion does not require resolution of this dispute.

**12. Disputed.** Sarepta admits [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED] See D.I. 463, ¶12. As NS Japan admits, [REDACTED]

[REDACTED]

[REDACTED] (D.I. 466, ¶2.15 (admitting D.I. 411, ¶2.15)) and that, while NS Pharma has been in [REDACTED] (D.I. 463, ¶21). Thus, there is nothing certain about [REDACTED] NS Japan further admits that, as of service of expert reports in this case, [REDACTED]

[REDACTED] D.I. 466, ¶2.12.

**13. Disputed.** Sarepta disputes this for the reasons in ¶11 above. That said, Sarepta's motion does not require resolution of this dispute.

**14. Disputed.** Sarepta admits that Mr. Hosfield's opening report includes the quotes.

[REDACTED] Rather, he determined "[REDACTED]

[REDACTED]

[REDACTED] D.I. 425-2 (Ex. 49), 80; *see also id.*, 81. Mr. Hosfield did not [REDACTED]

[REDACTED] Mr. Hosfield assumes, without analysis, that "[REDACTED]

[REDACTED]

[REDACTED] D.I. 425-2 (Ex. 49), 60; *id.* (Ex. 50), 112:15-22.

**15. Undisputed.**

**16. Disputed.** Sarepta admits that Mr. Hosfield's opening report includes the quote. Sarepta disputes that Mr. Hosfield's opening report provides support for his conclusions. For example, Mr. Hosfield relies only on Mr. Gendron's say-so that "[REDACTED]

[REDACTED]

[REDACTED]” D.I. 468-17 (Ex. 54), 69. Sarepta also disputes that “[REDACTED]  
[REDACTED] for the reasons  
in ¶6 above. That said, Sarepta’s motion does not require resolution of this dispute.

17. **Undisputed.** Sarepta admits that Mr. Hosfield’s opening report includes the quotes.

18. **Disputed.** Sarepta admits that Mr. Hosfield’s opening report states as such. Sarepta  
disputes that Mr. Hosfield’s conclusions and his bases for them are correct, at least because they

[REDACTED] As explained above in ¶12, there is nothing [REDACTED]  
[REDACTED]  
[REDACTED]  
[REDACTED]

[REDACTED] Further, [REDACTED]  
[REDACTED] D.I. 466, ¶2.16 (admitting D.I. 411, ¶2.16).

19. **Disputed.** Sarepta disputes NS Japan’s characterization of Mr. Jarosz’s opinions.  
NS omits that Mr. Jarosz also observed that NS Pharma is not a plaintiff in this litigation, and [REDACTED]  
[REDACTED]

[REDACTED] See D.I. 427-10 (Ex. 10), ¶¶169-74. Sarepta further notes that Mr. Hosfield—despite  
concluding otherwise—similarly [REDACTED]  
[REDACTED]

[REDACTED] See D.I. 425-2 (Ex. 49), 81-82.

20. **Undisputed.**

21. **Disputed.** Sarepta does not dispute that NS Japan and NS Pharma have not  
produced [REDACTED] Sarepta disputes the admissibility the Mr. Gendron’s declaration or his  
speculation about [REDACTED] for the reasons in Sarepta’s  
concurrently filed reply at 7 n.6. Sarepta further notes there is no record evidence of [REDACTED]  
[REDACTED].



III. **REPLY IN SUPPORT OF MOTION #3: SUMMARY JUDGMENT OF NO INEQUITABLE CONDUCT AND NO WALKER PROCESS FRAUD**

1. **Undisputed.**

2. **Undisputed.**

3. **Undisputed.**

4. **Undisputed.**

5. **Disputed.** The specification of the Wilton Patents states that “Table 39 below *includes* other antisense molecules tested at a concentration range of 50, 100, 300 and 600 nM.” D.I. 417-1 (Ex. 1), 64:46-47. But Sarepta’s motion does not require resolution of this dispute.

6. **Disputed.** Table 39 indicates that an ASO designed to target nucleotides 23 to 47 of human exon 53 was made and tested as a 2’-O-methyl phosphorothioate antisense oligonucleotide. D.I. 417-1 (Ex. 1), Table 1A. SEQ ID NO: 195 is assigned to that ASO. *Id.* But Sarepta’s motion does not require resolution of this dispute.

7. **Disputed.** Table 39 indicates that an ASO designed to target nucleotides 23 to 47 of human exon 53 (H53A(+23+47)) showed “very faint skipping to 50 nM.” D.I. 417-1 (Ex. 1), Table 39. But Sarepta’s motion does not require resolution of this dispute.

8. **Disputed.** The claimed function of “induc[ing] exon 53 skipping” should be considered in the context of the claimed invention as a whole, which is directed to a group of ASOs defined by multiple structural features that confer the claimed function. Support for the claimed invention is not limited to Table 39 of the Wilton Patents. *See, e.g.,* D.I. 427-2, ¶74. But Sarepta’s motion does not require resolution of this dispute.

9. **Undisputed,** but with clarification that [REDACTED]

[REDACTED] *See* Ex. 5, 16:24-25.

10. **Undisputed.**

[REDACTED]

11. **Undisputed**, but NS's statement of fact in Paragraph 11 is immaterial to Sarepta's motion for no inequitable conduct and no *Walker Process* fraud as discussed in the accompanying reply.

12. **Disputed.** [REDACTED]  
[REDACTED] *See, e.g.*, D.I. 468-4, SRPT-VYDS-0156178. Regardless, NS's statement of fact in Paragraph 12 is immaterial to Sarepta's motion for no inequitable conduct and no *Walker Process* fraud as discussed in the accompanying reply.

13. **Undisputed**, but with clarification that [REDACTED]  
[REDACTED]  
[REDACTED] Ex. 5, 49:1-50:2; Ex. 6, 154:18-23.

14. **Disputed.** [REDACTED]  
[REDACTED] *See, e.g.*, D.I. 468-4, SRPT-VYDS-0156178. Regardless, NS's statement of fact in Paragraph 14 is immaterial to Sarepta's motion for no inequitable conduct and no *Walker Process* fraud as discussed in the accompanying reply.

15. **Disputed.** The Wilton Patents describes SEQ ID NO: 195 as an ASO designed to target nucleotides 23 to 47 of human exon 53. *See* D.I. 417-1 (Ex. 1), Table 39. [REDACTED]  
[REDACTED] *See, e.g.*, D.I. 468-4, SRPT-VYDS-0156172. Regardless, NS's statement of fact in Paragraph 15 is immaterial to Sarepta's motion for no inequitable conduct and no *Walker Process* fraud as discussed in the accompanying reply.

16. **Undisputed.**

17. **Undisputed**, but NS's statement of fact in Paragraph 17 is immaterial to Sarepta's motion for no inequitable conduct and no *Walker Process* fraud.

[REDACTED]

18. **Disputed.** [REDACTED]

[REDACTED] D.I. 468-8, SRPT-VYDS-0158316-318. But Sarepta's motion does not require resolution of this dispute. [REDACTED]

[REDACTED]

[REDACTED]

19. **Undisputed.**

20. **Undisputed.**

21. **Undisputed.**

22. **Disputed.** The ASOs reported in Harding 2007 include "H53A(+23+47)." It does not mention "SEQ ID NO: 195." But Sarepta's motion does not require resolution of this dispute.

23. **Undisputed.**

24. **Undisputed,** but NS's statement of fact in Paragraph 24 is immaterial to Sarepta's motion for no inequitable conduct and no *Walker Process* fraud as discussed in the accompanying reply.

25. **Disputed.** Dr. Wilton testified that [REDACTED]

[REDACTED] and that [REDACTED]

[REDACTED] D.I. 471-2 (Ex. 7), 27:18-28:8, 28:19-25, 31:2-6. Dr. Fletcher also testified that

[REDACTED] D.I. 471-2 (Ex. 5), 124:12-125:2,

193:17-22. But Sarepta's motion does not require resolution of this dispute.

26. **Disputed.** Dr. Wilton testified that [REDACTED]

[REDACTED] and that [REDACTED]

[REDACTED] D.I. 471-2 (Ex. 7), 27:18-28:8, 28:19-25, 31:2-6. Dr. Fletcher also testified that

[REDACTED]

[REDACTED] D.I. 471-2 (Ex. 5), 124:12-125:2, 193:17-22. But Sarepta's motion does not require resolution of this dispute.

27. **Undisputed**, but with clarification that the Wilton Patents issued before Sarepta obtained the approval of Vyondys 53<sup>®</sup> (golodirsen) in any territory. [REDACTED]

[REDACTED]

28. **Undisputed**, but with clarification that the Wilton Patents issued before Sarepta obtained the approval of Vyondys 53<sup>®</sup> (golodirsen) in any territory. [REDACTED]

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January 26, 2024

**CERTIFICATE OF SERVICE**

I hereby certify that on January 26, 2024, I caused the foregoing to be electronically filed with the Clerk of the Court using CM/ECF, which will send notification of such filing to all registered participants.

I further certify that I caused copies of the foregoing document to be served on January 26, 2024, upon the following in the manner indicated:

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